IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, *Plaintiffs*, vs. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON, *Defendants*.	:	Civil Action No. 19-12107 (MEF) (SDA) *Document electronically filed*

CORRECTED BRIEF OF RELATOR ZACHARY SILBERSHER IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE EXPERT REPORTS

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INTRODUCTION AND SUMMARY OF CLAIMS

This case presents extraordinarily important issues involving pharmaceutical companies' abuse of the patent system to extend their drug monopolies beyond their lawful period, for the purpose of charging public healthcare programs (as well as patients and private payors) monopoly prices for important, life-saving medicine.

Plaintiff-Relator Zachary Silbersher alleges in his operative complaint (ECF No. 63) (the "Complaint") that defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson ("Defendants") caused the United States and Plaintiff States (collectively, the "Government") to pay hundreds of millions of dollars more for Defendants' prostate cancer drug, Zytiga (abiraterone acetate), than they should have. The Government overpaid monopoly prices because Defendants unlawfully obtained a fraudulent patent on Zytiga that they then used to exclude generic competitors. As a result, Medicare and other payors paid almost $10,000 per monthly prescription for Zytiga during the unlawful monopoly period; but now that the fraudulent patent has been invalidated, the price for generic Zytiga has plummeted to as low as a few hundred dollars. The gist of the Complaint therefore is this: When a drug company obtains a patent through fraud and then asserts the fraudulent patent against generic competitors to keep them off the market, then every single claim made to Government programs for the drug (such as Medicare or Medicaid reimbursements, or direct purchase by the Veterans' Health Administration for disbursement at VA hospitals) is a false claim under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA"), and state FCA analogues.

This case has already set important precedent. This matter was originally assigned to the Hon. Kevin McNulty, who denied Defendants' motion to dismiss. In a thorough and well-reasoned decision, this Court held that Relator's theories of fraud were valid, and the Complaint's

allegations sufficiently pleaded that Defendants' representations to the United States Patent and Trademark Office ("PTO") in obtaining the subject patent, U.S. Patent 8,822,438 ("the '438 patent"), were fraudulent. *United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 228 (D.N.J. 2021), *motion to certify appeal denied*, 2022 WL 225475 (D.N.J. Jan. 26, 2022).

To place in context the expert report that Defendants ask the Court to strike, Zytiga was originally covered by a chemical compound patent on Zytiga's active pharmaceutical ingredient, abiraterone acetate (often referred to as the '213 patent) which expired in December 2016. As the '213 patent drew close to its expiration, Defendants attempted to protect their patent monopoly for Zytiga by applying for a method of use patent claiming as inventive the coadministration of Zytiga with prednisone (which the FDA required because of observed side effects from taking abiraterone without a concomitant corticosteroid). The PTO rejected the application as obvious over the prior art multiple times. The patent application was allowed only after Defendants made misrepresentations and omissions of material fact regarding Zytiga's purported commercial success.

In short, Defendants misrepresented that prednisone coadministration purportedly caused Zytiga to achieve commercial success against competitors, supposedly proving that prednisone coadministration must not have been obvious, because an efficient market would have been expected to exploit such an invention earlier. Of course, this was spurious for many reasons, including the fact that the '213 patent was a blocking patent that kept other drug companies from selling abiraterone at all, and Defendants knew that prednisone coadministration was a central *weakness* of Zytiga compared with emerging treatments such as Xtandi® that avoided chronic steroid use (and the attendant side effects). (*See generally* Complaint, ¶¶ 8, 63-91) In fact, [redacted] Defendants' top executives at the highest

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levels were repeatedly warned that prednisone coadministration was one of the central competitive weaknesses of Zytiga [redacted]

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This Court held that the Complaint adequately pleaded viable theories of fraud under the FCA because of Relator's well-pleaded allegations that the claimed invention of co-administering abiraterone in combination with prednisone, is invalid because it was obvious to people of ordinary skill that abiraterone can be co-administered with prednisone. 576 F. Supp. 3d, at 218, *citing* Complaint ¶¶ 68-70, 76, 78. Accordingly, the patent application should have been rejected by the Patent Office—and for years, it repeatedly was rejected, until Defendants committed fraud. 576 F. Supp. 3d at 218-19 & 228-29, *citing* Complaint ¶¶ 75-81, 84; *see also, e.g.,* Complaint ¶ 87.

It is critical to note that the '438 patent has been invalidated, and Defendants' commercial success argument rejected, at least five times now: Three separate times by the PTO's Patent Trial and Appeal Board ("PTAB"); once by this Court; and once by the Federal Circuit. *See Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, No. IPR2016-00286, 2018 WL 454509, at *18 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms. Inc. v. Janssen Oncology, Inc.,* No. IPR2016-01332, 2018 WL 456305, at *18 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio Ag v. Janssen Oncology, Inc.,* No. IPR2016-01582, 2018 WL 456328, at *21 (P.T.A.B. Jan. 17, 2018); *BTG Int'l Ltd. v. Amneal Pharms LLC*, 352 F. Supp. 3d 352, 386 (D.N.J. 2018) (McNulty, J.); *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019). Indeed, if Defendants' commercial success argument had any merit, the PTAB and the courts could not have concluded that the patent was invalid.

There is no dispute that generic competitors did not begin to enter the market until after this Court invalidated the '438 patent in 2018, with most withholding entry until after the Federal Circuit affirmed the PTAB's invalidity decision in 2019. This means the Government was grossly overpaying for Zytiga from the time that the '213 patent expired in 2016 until after the Federal Circuit affirmed the '438 patent's invalidity in 2019. The only question is whether Defendants will be permitted to keep their improperly earned monopoly profits during this time. Under the FCA, the Government can recover its damages if Relator prevails in demonstrating that Defendants had the requisite culpable knowledge that their statements concerning commercial success were false.[1]

Therefore, Relator believes that the main issues to be resolved at trial are (i) whether Defendants were reckless, blindly indifferent, or simply lying when they falsely stated that Zytiga achieved commercial success *because* of prednisone coadministration; and (ii) how much the Government is able to recover as a result of Defendants' unlawfully maintained monopoly. The first issue (scienter) is a factual determination for the jury. The second issue, concerning damages, requires complex quantitative analysis of millions of data points provided by various government agencies, Defendants, and multiple generic competitors. This is where the Revised Report of Dr. Hal Singer fits in—and Defendants now move to strike the supplemental information resulting from newly obtained data.

As the preceding discussion shows, Dr. Singer's expert opinion is a critical part of Relator's case because it provides a robust, meticulous, and highly credible analysis demonstrating that the Government is entitled to recover billions of dollars in damages and statutory penalties. As detailed in paragraphs 7 through 11 and Appendix 2 in the Revised Report, Dr. Singer is a widely respected

[1] Under the FCA, a defendant is liable for making false statements with "actual knowledge," with "deliberate ignorance of the truth or falsity of the information," or with "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). Specific intent is not required. *Id.*

economist and academic who has authored numerous books and academic articles appearing in dozens of legal and economic journals. He has testified before Congress on the interplay between antitrust and sector-specific regulations; his scholarship and testimony have been widely cited by courts and regulatory agencies, including the FCC, FTC, and the DOJ; and his expert testimony has been accepted in ten significant antitrust cases and five consumer protection actions. (*See* Greenberg Decl. Ex. B; Defendants' Exhibit D.)

* * *

With this background, Relator respectfully opposes Defendants' motion (ECF No. 372) seeking to strike:

(i) the Revised Expert Report of Hal J. Singer, Ph.D., dated August 27, 2024; and

(ii) certain language in Relator's expert reports—***virtually identical to language used by Defendants*** in the prior patent litigation before Judge McNulty[2]—reserving testimony "as to any subject matter within [their] area of expertise that may be useful to inform the Court . . . ."

[2] Defendants use virtually identical language in their own report. As one example, the following language is from the expert report of Dr. Matthew Rettig that Defendants submitted in the underlying patent litigation that led to the invalidation of the Zytiga patent at issue in this case:

> "***I may testify further as to subject matter within my area of expertise which will be useful to inform the judge as to the bases for my opinions***."

(Janssen Biotech, Inc., *et al.* Expert Report of Dr. Matthew Rettig, ¶ 199, attached as **Exhibit C** to the accompanying Declaration of Bruce D. Greenberg ("Greenberg Decl.").

As Defendants know, this language is sometimes used by parties to reserve the right of the expert to testify to subject matter as may be *permitted* by the rules, such as in rebuttal to another expert, or which fairly arise from, and are related to, the opinions contained in the report. Relator has never stated (and does not intend) that the subject language reserves the right to testify as to matters not otherwise permitted by the rules, and Defendants do not identify any proposed testimony that would be impermissible. Thus, Defendants have raised a dispute that does not actually exist.

In this regard, Relator notes that Defendants have failed to submit the required certification that Defendants have conferred in a "good faith effort" to resolve the issues without intervention of the Court. *See* Local Rule 37.1(b)(1). Defendants wrote an email to Relator's counsel on September 18 asking Relator to withdraw the referenced language, and Relator responded on September 20 stating that he would not do so. However, there was never a meet and confer (either by telephone or videoconference) during which Defendants made a good faith effort to identify whether Relator intended to proffer any impermissible expert opinion. This explains why Defendants did not submit a Rule 37.1 certification—because the good faith confer requirement was not satisfied.

This therefore raises a threshold issue as to whether the present motion is a "discovery" dispute within the meaning of Rule 37.1. Assuming Defendants did not intend to violate Rule 37.1, they therefore must have believed their motion to strike an expert report was not a "discovery" dispute. If so, Defendants should have filed a noticed motion to the Court, instead of submitting a letter brief to the Special Master, whose appointment embraced only "discovery" issues.

Relator has filed a letter to the Court requesting clarification whether this and any future expert dispute, particularly a motion to strike an expert report, should be assigned to the Special Master. (ECF No. 375.)

The Court should deny Defendants' motion. As to the first issue, the Revised Report of Dr. Hal Singer is proper because the supplemental information as to which Defendants object primarily consisted of updating the damage calculations in light of new and additional data that was provided by the Centers for Medicare & Medicaid Services ("CMS") on August 13, 2024—only two weeks before Relator served the supplemented report on August 27, 2024, and *after* the date that the original report was served on August 7, 2024, as corrected, August 9, 2024. (Greenberg Decl. ¶ 6.) Dr. Singer "did not modify any methodologies or [ ] conclusions" in the sense of how healthcare agencies were damaged by Defendants' fraudulent scheme or proper the methodology by which such damages should be calculated, but only as to the calculated output based on previously unavailable data inputs. (*See* Greenberg Decl. **Exhibit D**, at ¶ 1.)

~~Moreover, the missing data that were recently provided by CMS should have been—but was not—produced by Defendants pursuant to Relator's Request for Production Nos. 24 & 32. (*See* Greenberg Decl. **Exhibit E.**) Therefore, the need to supplement resulted from Defendants' own discovery failures.~~

Finally, Defendants do not even attempt to demonstrate that, much less how, they were prejudiced by the supplemented information. As explained below, Defendants have six months to serve expert reports, whereas Relator served his expert reports within two months of the end of fact discovery, leaving Defendants an additional four months. Accordingly, Defendants' opening and rebuttal reports are not due until December 9, 2024.

As to the second issue, Defendants do not identify any impermissible testimony proffered. As discussed in footnote 2, supra, Defendants have used virtually identical language when submitting their own reports in the underlying patent infringement litigation relating to the '438

patent, which simply means the expert is reserving the right testify as to any matters that would otherwise be permitted under the rules.

SPECIFIC FACTS RELATING TO THE REVISED SINGER REPORT

Relator served Dr. Singer's original report on August 7, 2024, which was the deadline for Relator to serve expert reports. Two days later, on August 9, Relator served an errata and corrected report because two tables included in the report did not accurately update data. Defendants do not move to strike those corrections.

The original and corrected report from Dr. Singer analyzed over a million transaction data points relating to Zytiga and generic Zytiga primarily produced by: (i) Defendants in response to Relator's document requests; (ii) Centers for Medicare & Medicaid Services ("CMS"), pursuant to a *Touhy* subpoena[3] originally served on September 7, 2023 (and re-served with the Court's signature at the request of CMS on February 5, 2024); and the United States Department of Veterans' Affairs, re-served with the Court's signature as requested by the agency on December 20, 2023. Based on the data received by these sources, Dr. Singer's original report analyzed the transaction data for Zytiga and generic Zytiga for over a dozen drug companies. (Greenberg Decl. Ex. B, at Appendix 3, starting at numbered page 81 (or 85 of 109 in the PDF).

Dr. Singer's original and corrected report noted that the data produced by Defendants and the Government agencies did not include transaction data from Patriot Pharmaceuticals, which sold an authorized generic version of Zytiga under a license from Defendants. Noting this missing data, Dr. Singer noted at footnote 163 of his original report that because of the missing data,

> authorized generic purchases are excluded entirely from my estimate of damages using overcharge, making these calculations conservative. As I demonstrate in Appendix 7, the authorized generic was a significant supplier in the market and its exclusion

[3] Named after the decision in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

> likely decreases my damages estimate significantly. I reserve the right to supplement my analyses should suitable price and quantity data become available to me.

(*See* Greenberg Decl., Ex. D, at Appendix 8, ¶ 103; Defendants' Exhibit D, at ¶ 84 & n. 163 at internal page 49, or 53/102 of the PDF.)

CMS produced the missing data on August 13, 2024, after Dr. Singer's original report was served (as corrected on August 9, 2024). Two weeks later, on August 27, 2024, Relator served Dr. Singer's Revised Report. Relator served a redline of the changes (Greenberg Decl., Ex. D) to Defendants on August 28, 2024. The changes are described in paragraph 1, stating that the:

> supplemented and revised report reflects CMS's updated Medicare Prescription Drug Event (PDE) data, which now includes drug utilization information for the abiraterone acetate authorized generic sold by Patriot Pharmaceuticals, LLC (which I understand is a wholly owned subsidiary of Johnson & Johnson and its Janssen subsidiaries). The updated data from CMS was not available to me at the time I submitted my Damages Report. The revisions in this supplemented and revised Damages Report ("Revised Report") reflect updates to results in light of the newly available data, and they do not modify any methodologies or my conclusions.

(*See* Greenberg Decl., Ex. D, ¶ 1.) Dr. Singer made conforming changes in the rest of his report. For example, Dr. Singer substantially deleted Appendix 7, which was necessary only to address the omission of transaction data relating to the authorized generic sales that are now included in the report. (*See* Greenberg Decl., Ex. D, at internal pages 97 through 99, or pages 101-03 / 109 of the PDF.) Dr. Singer also added Appendix 8, which compares the calculations in the original report and the Revised Report to make the changes transparent and clear. (*See* Greenberg Decl., Ex. D, at internal pages 103 through 105, or pages 107-09 / 109 of the PDF.)[4]

[4] Dr. Singer also made a few typographical corrections and updated Table 6 to ensure that the weighted averages were calculated only during times when there was a positive overcharge—which change was *de minimis* and "did not alter the calculated generic overcharges." (Greenberg Decl., Ex. B, at ¶ 1.)

The omission of the authorized generic data was not the fault of CMS, which provided the additional data upon Relator's request~~, but rather resulted from Defendants' deficient discovery responses~~.

Relator provided CMS with the National Drug Codes (NDCs) for abiraterone acetate.[5] The first five digits of an NDC corresponds with a unique "Labeler" (*i.e.*, the drug manufacturer or distributor). The labeler code for Patriot Pharmaceuticals is 10147.[6] In contrast, the relevant labeler code for Defendants (assigned to defendant Janssen Biotech, Inc.) is 57894.[7] As can be seen from the foregoing database queries of the FDA directory, there are no NDCs listed for Patriot Pharmaceuticals relating to Zytiga or abiraterone. There are, however, three NDCs listed for Defendants relating to Zytiga, with one product code (the next three digits) ending in -150, and two others ending in -195. Using the NDCs for abiraterone available at the FDA's database, no data was returned for any authorized generics from Patriot Pharmaceuticals.

In the process of completing Dr. Singer's report, however, Relator discovered that the data provided by Defendants and the Government agencies, including CMS, omitted data for authorized generics sold by Patriot. Relator discovered on his own through other sources that the authorized generic sales sold through Patriot were actually conducted under Defendants' NDC Code 57895, but utilizing a different and unlisted product code (155) that does not appear in the FDA database.

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[5] *See* FDA NDC Directory, available at: https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=NONPROPRIETARYNAME&type=abiraterone+acetate.

[6] See FDA NDC Directory, available at: https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=LABELERNAME&type=patriot.

[7] *See* FDA NDC Directory, available at: https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=LABELERNAME&type=janssen+biotech.

Nevertheless, the use of Defendants' unique labeler code (instead of Patriot's labeler code) demonstrates that the authorized generic sales of Zytiga through Patriot were sold pursuant to Defendants' New Drug Application~~, and thus should have been considered either Zytiga, or generic Zytiga, sales when Defendants responded to Relator's discovery requests. The transaction data and relevant NDC code therefore should have been (but were not) provided by Defendants to Relator during fact discovery~~.

~~Defendants were obligated, but failed, to provide the NDC code and transaction data for its authorized generic sales through Patriot. Relator's First Amended Requests for Production of Documents, which were served in early 2022, specifically asked for (and Defendants' response obligated them to produce) "[a]ll documents concerning the actual or projected price, costs, revenues, and/or profits in the United States for Zytiga or Generic Zytiga." (Greenberg Decl., Ex. E, at No. 24.) Relator also requested, and Defendants were obligated to produce, "Electronic data . . . sufficient to identify all sales of Zytiga or Generic Zytiga to the Government . . . ." (Greenberg Decl., Ex. E, at No. 32.) Despite these clear requests, the data provided by Defendants and given to Dr. Singer did not include the authorized generic Zytiga sales sold through Patriot.~~

~~Moreover, in Relator's Notice of 30(b)(6) Deposition served on Defendants on February 7, 2024, Topic 18 requests Defendants to produce a corporate representative to testify about the "sale of any Authorized Generic of Zytiga." Had Defendants timely complied, the missing authorized generic data and relevant NDC code would have been provided or identified, and Dr. Singer would have been able to obtain the relevant data prior to August 7, 2024. However, Defendants wrongfully refused for months to provide such a witness. Finally, on July 10, 2024, the Special Master ordered Defendants to produce a corporate representative to testify with respect to Topic 18. (*See* ECF No. 370, at 11.) The earliest date offered by Defendants was October 4,~~

~~2024. But as that date approached, on September 30, 2024, Defendants unilaterally cancelled the deposition over Relator's objections, in flagrant disregard of the Special Master's July 10 Order. (*See* Greenberg Decl., Ex. F.)~~

Finally, Defendants have suffered no prejudice from the service of the Revised Report on August 27, 2024. Under the latest scheduling order (ECF No. 335), fact discovery should have closed on June 7, 2024. Relator timely served his opening expert reports two months later, on August 7, 2024. This gave Defendants six months from fact discovery to serve their opening and rebuttal expert reports (by December 9, 2024). Thus, even with the Revised Report having been served on August 27, Defendants will still have had over three months to serve their rebuttal reports—which is still a much longer time period than the time period imposed on Relator. Surely, one of the largest companies in the world should be able to manage that schedule.

Moreover, counsels' correspondence demonstrates that the August 27 update of Dr. Singer's calculations did not delay Defendants' preparations or inconvenience them at all. On August 29, Defendants wrote to Relator raising several issues they had with Dr. Singer's report. (*See* Greenberg Decl., Ex. G.) By this time, Defendants had received the supplemented Revised Report and a redline of the changes. While Defendants requested certain workpapers generated by Dr. Singer (such as electronic versions of the datasets used in his report, as well as the coding and formulae embedded in his models), Defendants did not mention, or object to, the service of the Revised Report. Nor did Defendants raise any objections or claim prejudice during a subsequent meet and confer between the parties on September 5, 2024. To the contrary, Defendants were just then beginning to ask for the "computer codes/programs" to replicate and analyze Dr. Singer's calculations, and they even pushed off a meet and confer date to discuss the logistics for the data transfers for a week after the earlier dates that Relator offered. (*Id.*) Thus, it is clear that the updates

to Dr. Singer's calculations on August 27 had absolutely no effect on Defendants' ability to prepare a rebuttal report that is not even due for another two months, on December 9, 2024.

ARGUMENT

I. The Court Should Not Strike Dr. Singer's Revised Report.

Federal Rule of Civil Procedure 26(a)(2) provides that expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B). The Rule permits parties to "supplement these disclosures when required under Rule 26(e)." Fed. R. Civ. P. 26(a)(2)(E).

Rule 26(e) requires that a party who has served an expert witness report "must supplement or correct" the report "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. Proc. 26(e). "Any additions or changes" to the information included in an expert witness report "must be disclosed by the time the party's pretrial disclosures under Rule 26(a)(3) are due." *Id.*

Pursuant to Rule 37(c)(1), if "a party fails to provide information as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Nevertheless, supplementation under Rule 26(e) is appropriate "to permit supplementation in instances such as when an expert receives newly produced information or discovers numerical errors in her calculations after submitting her expert report." *In re Lamictal Direct Purchaser Antitrust Litig.*, 2022 WL 190651, at *2 (D.N.J. Jan. 21, 2022) (citing *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, 2019 WL 581544, at *3 (D.N.J. Feb. 13, 2019)).

Nowhere do Defendants cite, much less grapple with, the factors the Third Circuit has

established for determining whether to strike an expert disclosure. This alone justifies rejecting their motion. Under Third Circuit precedent, when deciding whether to exclude expert testimony under Rules 37(c)(1) and 26(e), a district court should weigh: (1) prejudice or surprise to the moving party; (2) the ability of the moving party to cure any prejudice; (3) the extent to which allowing the evidence would disrupt the orderly and efficient progress of the case to trial; (4) bad faith or willfulness in failing to comply with the court's order; and (5) the importance of the testimony sought to be excluded. *Nicholas v. Pa. State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000) (discussing the first four factors); *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (instructing that "the importance of the excluded testimony" should be considered because "exclusion of critical evidence is an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order") (cleaned up).

In applying these factors, courts have recognized that the "Third Circuit has, on several occasions, manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony." *United States for Use of Colorado Custom Rock Corp. v. G&C Fab-Con, LLC*, 2024 WL 624040, at *6 (D.N.J. Feb. 14, 2024) (quoting *ABB Air Preheater, Inc. v. Regenerative Env't Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996)). Indeed, because "[t]he exclusion of critical evidence is an extreme sanction, this remedy should not be imposed where an untimely or improper expert disclosure amounts to only a slight deviation from pre-trial notice requirements or occasions only slight prejudice' to the movant." *Dal-Far Realty, LLC v. Peerless Indem. Ins.*, 2017 WL 11476223, at *3 (D.N.J. June 12, 2017) (internal quotations omitted).

Applying the five factors under *Nicholas* and *Konstantopoulos* in light of the strong aversion in this Circuit against exclusion absent "extreme neglect or bad faith," Defendants'

motion clearly should be rejected. First, there is no surprise to Defendants, because Dr. Singer's original report specifically disclosed that data relating to Defendants' authorized generic sales through Patriot were missing, and that the report would be updated when the data was received from CMS. Nor have Defendants articulated or demonstrated any credible prejudice. It is clear they had not even begun to quantitatively analyze Dr. Singer's calculations by the time the Revised Report was served, because they were just getting around to request the electronic formulae, codes, and electronic datasets he constructed that would have permitted them to replicate and analyze Dr. Singer's calculations. (Dr. Singer properly identified in his original report the relevant data from CMS, the VA, and Defendants' production upon which he constructed his models.) Moreover, Defendants have until December 9, 2024 to serve their rebuttal reports—which will be over three months from the date that Relator served Dr. Singer's Revised Report, and one month longer than Relator had to serve his original reports.

Second, Defendants have not even attempted to demonstrate an inability to cure any prejudice. If Defendants did suffer any prejudice from the 20-day period between service of the original report to the Revised Report, they could have easily asked for a similar extension to serve their rebuttal reports, particularly since expert depositions are not scheduled to be completed until May 12, 2025. (ECF No. 335.) The reason that Defendants have not tried to cure any prejudice is because there has been no prejudice at all, especially given the nature of the revisions, which did not alter Dr. Singer's methodology. But even if the Court believes Defendants have been prejudiced, the Court could grant Defendants an additional another three weeks to prepare any rebuttal report to Dr. Singer's report, which would indisputably cure any possible prejudice.

Third, the twenty days it took for Relator to serve the Revised Report has no effect on the orderly and efficient progress of the case to trial, and Defendants do not claim otherwise. Nor can

they. No trial date has been set, and Defendants have until May 12, 2025, to complete expert depositions.

Fourth, there has been no bad faith or willfulness by Relator. ~~To the contrary, it is Defendants who have breached their discovery obligations, including by failing to provide the transaction data for authorized generic sales in response to Relator's Requests for Production Nos. 24 and 32. Defendants have also refused to produce a 30(b)(6) witness to testify to authorized generic sales, in contravention of the Special Master's July 10, 2024 Order directing them to do so. In contrast,~~ Relator sought on an expedited basis the missing data from CMS, and promptly served a supplemental Revised Report within two weeks.

Fifth, the importance of Dr. Singer's testimony is beyond doubt. Defendants even concede that striking his Revised Report would mean that the Government could potentially allow Defendants to avoid paying $150 million in unlawful overcharges and false claims to the Government. (Defendants' Br. at 5; Greenberg Decl., Ex. D, at Appendix 6, Tables 1-3 at internal pages 91-93, or pages 95 to 97 of 109 of the PDF.)

Defendants also rely on the out-of-Circuit decision in *DAG Enters., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 110 (D.D.C. 2005). To begin with, the standard applied by the *DAG* court was completely different than what the Third Circuit has established for the courts in this Circuit—including application of the five-factor test under *Nicholas* and *Konstantopoulos*, and the strong aversion to striking expert reports, as recognized by *G&C.* Moreover, the *DAG* case presents a materially different factual context. As the court noted in *DAG*, the parties seeking to supplement their expert report in that case "were not seeking to *supplement* their previous reports by filing updated information that brought their old figures to present; rather, they were seeking to throw out the old figures altogether, rely on entirely new values premised upon a completely different

theory of damage calculation, and draft new expert reports . . . .” 226 F.R.D. at 101. That is very different from this case.

Finally, Defendants rely on *Ezaki Glico Kabushiki Kaisha v. Lotte Int’l Am. Corp.*, 2019 WL 581544 (D.N.J. Feb. 13, 2019), but the facts of that case are a far cry from here. There, the defendant who attempted to supplement its expert report waited until the day of the expert’s deposition (minutes before the deposition was scheduled to start) to serve the supplemental report, while insisting that the deposition continue. Moreover, there were substantial changes to the report, including to the methodology by which the damages expert calculated damages. The supplemental report also was not necessitated by additional data that was previously unavailable. In other words, *Ezaki* is completely different from this case. Nevertheless, even with the flagrant disregard of the discovery rules presented in *Ezaki*, the court held that striking the supplemental report “would be a harsh sanction that does not appropriately redress the violation at issue.” *Id.*, at *6. The court therefore allowed the supplemental report, but it afforded the moving party the opportunity to cure any prejudice to them. *Ezaki* therefore cuts strongly against Defendants.

II. The Court Should Deny Defendants’ Other Requested Relief.

Defendants do not identify any impermissible expert testimony being proffered, and Defendants have used virtually identical language when submitting their own reports. Defendants also failed to meet and confer with Relator in good faith, which would have clarified that Relator’s experts are simply reserving the right to testify as to any matters that would otherwise be permitted under the rules. Therefore, the Court should not grant Defendants’ motion.

Defendants also ask the Court to prohibit any future supplemental reports. There is no basis for the Court to determine such a request at this time, and Defendants offer no authority for the Court to issue an order that would modify the procedures set forth in Rules 26 and 37.

CONCLUSION

For the foregoing reasons, Defendants' motion should be denied in its entirety.

Dated: October 157, 2024

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